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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,205	10/29/2001	Richard Anthony Godwin Smith	62130-0002	2596

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EXAMINER	
ROOKE, AGNES BEATA	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,205	SMITH ET AL.	
	Examiner	Art Unit	
	Agnes B. Rooke	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,14 and 16-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9, 14, 16-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/14/2006 has been entered.

Claims 1-8, 10-13, and 15 are cancelled. Claims 9, 14, and 16-24 are pending.

This application is a 371 of PCT/GB00/00834 filed on 03/08/2000, which claims foreign priority to UNITED KINGDOM 990553.0 filed on 03/10/1999.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 9 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 9, the "immunoregulatory activity" is not definite because it must be stated for example that the activity refers to a particular receptor etc.

Claim 24 contains the trademark/trade name SOLTRAN. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second

paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the solution used and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 9, refers to an "immunoregulatory activity" of a fragment of SEQ ID NO:1. It should be disclosed in the claim to what particular activity or receptor the Applicants refer to etc. The written description requirement is not satisfied because the structure of the fragment does not correspond with its specific function.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9, 14, 16, 17, 19-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Rittershaus et al. (U.S. 6,193,979 B1). Rittershaus et al. teach that compositions that comprise a complement-related protein (CR1) in combination with the Lewis X antigen or the sialyl Lewis X antigen, a carbohydrate moiety. Rittershaus et al. teach a soluble CR1 peptide, sCR1, and their use where organs prepared for transplant are perfused with the peptides. Alternatively, organs for transplantation are stored in solutions containing the peptides (see column 36, line 15). Rittershaus et al. teach formulations of the peptides with excipents including, for example, pharmaceutical grades of mannitol (see column 37 regarding claim 14). The soluble CR1 peptides of Rittershaus et al. would inherently comprise SCRs, the sequence of 2 to 197 of SEQ ID NO:1, and membrane binding elements consistent with claims 16-17. Thus, the reference clearly anticipates the invention as recited in the claims.

Further, in Figure 4, column 11, Rittershaus et al. describes the protective effects of sCR1 from lung injury induced by CVF; where Figure 4B shows the measurement of the reduction over control of hemorrhage assured by a red blood cell leakage into the lung from the blood vessel, for example. (see column 11 regarding claims 19-21).

Claims 9, 14, 17, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith et al. (U.S. 6,713,606 B1). Smith et al. teach CR1, which would comprise SCRs and membrane binding elements consistent with claim 17. Further, Smith et al. teach soluble CR1 polypeptide that is derivatized with a myristoyl group (See column 17, line 55 regarding claim 18). At column 18, Smith et al. teach the use of peptides for Post-Ischemic Reperfusion Conditions. Thus, the reference clearly anticipates the invention as recited in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9, 14, 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Rittershaus et al. (U.S. 6,193,979 B1) in view of Smith et al. (U.S. 6,713,606 B1). Rittershaus et al. teach compositions that comprise a complement-related protein (CR1) in combination with the Lewis X antigen or the sialyl Lewis X antigen, a carbohydrate moiety. Rittershaus et al. teach a soluble CR1 peptide, sCR1, and their use where organs prepared for transplant are perfused with the peptides. Alternatively, organs for transplantation are stored in solutions containing the peptides (see column 36, line 15). Rittershaus et al. teach formulations of the peptides with excipents including, for example, pharmaceutical grades of mannitol (see column 37 regarding

claim 14). The soluble CR1 peptides of Rittershaus et al. would inherently comprise SCRs, the sequence of 2 to 197 of SEQ ID NO:1, and membrane binding elements consistent with claims 16 and 17.

Further, in Figure 4, column 11, Rittershaus et al. describe the protective effects of sCR1 from lung injury induced by CVF; where Figure 4B shows the measurement of the reduction over control of hemorrhage assured by a red blood cell leakage into the lung from the blood vessel, for example. (see column 11 regarding claims 19-21).

Rittershaus et al. do not teach complement–related protein (CR1) in combination with a myristoyl group.

Smith et al. teach soluble CR1 polypeptide derivatized with a myristoyl group (see column 17, line 55 regarding claim 18).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the myristoylated CR1 polypeptide of Smith et al. for the CR1-lewis antigen composition in the method of perfusing an organ, where the organ is a lung, a heart, or a kidney, for a prevention of ischemic reperfusion injury as taught by Rittershaus et al. A person of ordinary skill in the art would have been motivated to make the above substitution because both compositions are taught as having uses in the prevention of post-ischemic reperfusion injuries. Thus, a person of ordinary skill in the art would have expected success in perfusing an organ with the myristoylated CR1 polypeptide of Smith et al. Therefore, the claimed invention is within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Applicants' Arguments and Examiner's Response

In the Remarks submitted on 04/13/2006, Applicants state that Rittershaus et al. relate to a composition comprising complement proteins related to CR1, where the composition mediate binding to membranes only if a protein is expressed in a membrane bound form on cells; and that CR1 was modified by glycoform manipulation and that such modification is not possible for SEQ ID NO:1. However, Rittershaus et al. would anticipate claims as currently written, because the structure of CR1 disclosed by Rittershaus et al. is the same as the structure of the protein in the instant invention.

Applicants also discuss the rejection over Smith et al. where they state that Smith et al. discloses soluble derivatives of soluble peptides that can be used according to the invention where the instant claims are not solely directed to such composition but to methods of use for the soluble derivatives. However, the rejection over Smith is correct because Smith et al. teach that: 1) CR1 and membrane binding elements are consistent with claim 17; 2) soluble CR1 polypeptide is derivatized with a myristoyl group consistent with claim 18; and 3) the claimed peptides are used for Post–Ischemic Reperfusion Conditions. Thus, the reference clearly anticipates the invention as recited in the claims.

Applicants further discuss obviousness rejection that examiner did not provide factually-supported rationale for performing a method that would require substituting Rittershaus et al. transplant compound with Smith et al. compound. However, as stated

in the rejection, a person skilled in the art would have been motivated to make the above substitution because both compositions are taught as having uses in the prevention of post-ischemic reperfusion injuries, thus one would expect a great success in perfusing an organ with the myristoylated CR1 polypeptide of Smith et al.

Conclusion

No claims are allowed.

Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for unpublished applications is available through Private PAIR or Public PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JON WEBER
SUPERVISORY PATENT EXAMINER